Transcatheter Mitral Valve Replacement in Patients With Previous Aortic Valve Replacement

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Abstract: BACKGROUND Transcatheter mitral valve replacement (TMVR) may mature to become a therapeutic option for high-risk patients with severe mitral regurgitation (MR), particularly in patients at high or prohibitive surgical risk. MR patients with preexisting aortic valve prosthesis have been excluded from most TMVR trials because of the potential risks of left ventricular outflow tract obstruction or interaction between the TMVR anchoring mechanism and the aortic prosthesis. We describe the procedural and short-term outcomes of transapical TMVR with the Tiara valve in patients experiencing severe symptomatic MR with previous aortic valve replacement (AVR). METHODS AND RESULTS Twelve consecutive high surgical risk patients (11 men; mean age, 75±6 years) with aortic valve prosthesis and severe MR underwent TMVR with Tiara valve. Aortic valves were mechanical in 5 and biological in 7 patients, while 1 patient had previously undergone implantation of a transcatheter valve within a failed bioprosthetic surgical valve. Six patients (50%) had undergone redo surgical aortic valve replacement. Clinical characteristics of the group include prior mitral valve repair in 2, prior coronary bypass grafting surgery in 5, chronic atrial fibrillation in 7, renal failure in 9, and pacemaker/cardiac resynchronization device in 9 patients. Mean Society of Thoracic Surgery score and EuroSCORE II were 10.5±4.4 and 12.4±3.7, respectively. Mean baseline left ventricular ejection fraction was 35.5±5.3% (range, 30%-45%). The Tiara valve was implanted uneventfully in all patients. Device migration or left ventricular outflow tract obstruction was not observed. No patient required conversion to open heart surgery or periprocedural hemodynamic support. Procedural success was 100% with no death, MI, stroke, major bleeding, or access site complications at 30 days. MR was eliminated in all 12 patients immediately after implantation. CONCLUSIONS Transapical mitral valve replacement with the Tiara valve in high-risk patients with severe MR and aortic valve prostheses is technically feasible and can be performed safely.

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ORIGINAL ARTICLE

Transcatheter Mitral Valve Replacement in Patients With Previous Aortic Valve Replacement

See Editorial by Guerrero and Rihal

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BACKGROUND: Transcatheter mitral valve replacement (TMVR) may mature to become a therapeutic option for high-risk patients with severe mitral regurgitation (MR), particularly in patients at high or prohibitive surgical risk. MR patients with preexisting aortic valve prosthesis have been excluded from most TMVR trials because of the potential risks of left ventricular outflow tract obstruction or interaction between the TMVR anchoring mechanism and the aortic prosthesis. We describe the procedural and short-term outcomes of transapical TMVR with the Tiara valve in patients experiencing severe symptomatic MR with previous aortic valve replacement (AVR).

METHODS AND RESULTS: Twelve consecutive high surgical risk patients (11 men; mean age, 75±6 years) with aortic valve prosthesis and severe MR underwent TMVR with Tiara valve. Aortic valves were mechanical in 5 and biological in 7 patients, while 1 patient had previously undergone implantation of a transcatheter valve within a failed bioprosthetic surgical valve. Six patients (50%) had undergone redo surgical aortic valve replacement. Clinical characteristics of the group include prior mitral valve repair in 2, prior coronary bypass grafting surgery in 5, chronic atrial fibrillation in 7, renal failure in 9, and pacemaker/cardiac resynchronization device in 9 patients. Mean Society of Thoracic Surgery score and EuroSCORE II were 10.5±4.4 and 12.4±3.7, respectively. Mean baseline left ventricular ejection fraction was 35.5±5.3% (range, 30%–45%). The Tiara valve was implanted uneventfully in all patients. Device migration or left ventricular outflow tract obstruction was not observed. No patient required conversion to open heart surgery or periprocedural hemodynamic support. Procedural success was 100% with no death, MI, stroke, major bleeding, or access site complications at 30 days. MR was eliminated in all 12 patients immediately after implantation.

CONCLUSIONS: Transapical mitral valve replacement with the Tiara valve in high-risk patients with severe MR and aortic valve prostheses is technically feasible and can be performed safely.

Key Words: humans ■ male ■ mitral valve ■ mitral valve insufficiency ■ stroke

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WHAT IS KNOWN

- Mitral regurgitation is under-referred and undertreated.
- Transcatheter mitral valve interventions, including repair and replacement, are potential options for high-risk surgical mitral regurgitation patients.
- Transcatheter mitral valve replacement is contraindicated in patients with previous aortic valve replacement because of the potential interaction of the transcatheter mitral valve replacement device with the aortic prosthesis.

WHAT THE STUDY ADDS

- Transcatheter mitral valve replacement with the Tiara device is safe and effective in treating patients with symptomatic mitral regurgitation.
- Transcatheter mitral valve replacement with the Tiara device in patients with an existing aortic prosthesis can be performed safely.
- Excellent clinical and hemodynamic outcomes were seen.

With the ongoing technological advancement in the field of transcatheter mitral valve replacement (TMVR), it is expected that TMVR will eventually become an alternative treatment to mitral valve (MV) surgery for patients with severe mitral regurgitation (MR). Compared with transcatheter aortic valve replacement (AVR), TMVR seems to be more complex and more challenging. Among the challenges TMVR technology faces are the asymmetrical annulus, the irregular geometry of MV leaflets, the large dimensions, the high-pressure gradient across the MV (closing pressure), the absence of a calcific structure for anchoring, the complex subvalvular anatomy, and the risk of left ventricular outflow tract (LVOT) obstruction.[1] LVOT obstruction is described not only after TMVR[2,3] but also after mitral surgery with annuloplasty rings and prostheses, where it may lead to catastrophic outcomes.[4–6] The risk of LVOT obstruction after TMVR may be higher in patients with preexisting aortic valve prosthesis because patients with prior aortic stenosis often have left ventricular (LV) hypertrophy and small LV cavity, and the frame of the aortic prosthesis can extend into the LVOT.

In addition, the anchoring mechanism of TMVR may interfere with the proper functioning of an aortic prosthesis, especially a mechanical valve. Consequently, aortic prostheses have been considered a relative contraindication to TMVR in these patients.

The Tiara TMVR device (Neovasc, Inc, Richmond, Canada)—a transcatheter mitral bioprosthesis—was designed to fit the asymmetrical and multiplanar mitral annulus. It is fabricated using cross-linked bovine pericardial tissue leaflets mounted inside a self-expanding nitinol frame, which can be crimped onto a short, sheathless transapical delivery system. The D-shaped Tiara valve is designed to match the natural orifice of the MV, avoiding impingement of the LVOT and to prevent any interference with the aortic valve or prosthesis (Figure 1).[7–11]

The Tiara valve is currently being evaluated in 2 ongoing clinical trials: TIARA-I—an early feasibility trial in the United States, Canada, and Belgium—and TIARA-II—a European Conformité Européenne Mark Trial in Germany, Italy, and the United Kingdom. In addition, patients have also been treated under compassionate programs in Canada, Italy, Germany, Israel, and Switzerland.

In this retrospective analysis, we describe, for the first time, the periprocedural and short-term outcomes of patients with severe MR and previous AVR treated with the Tiara TMVR system. We show that with an effective patient screening, and a valve design that fits into the native mitral apparatus, LVOT obstruction is avoided.

METHODS

The data, analytic methods, and study materials will not be made available to other researchers for purposes of reproducing the results or replicating the procedure.

Patients

This is a retrospective analysis of the baseline, periprocedural, and ≤30-day postprocedural data, collected on 12 consecutive patients with previous surgical AVR who underwent TMVR using the Tiara system. All implant procedures were approved by the institutional and national clinical research committees.

Eligibility for Tiara implantation was determined by a central screening committee after evaluating the relevant clinical data for each patient, and the core laboratories analyses of the echocardiographic studies (TTE and TEE), and computed tomography (CT).

Imaging

Echocardiographic eligibility criteria were severe symptomatic MR (stage D) by 2014 American Heart Association/American College of Cardiology Valvular Heart Disease Guidelines classification, as determined by the Echo Core Laboratory, as well as anatomic eligibility criteria for the 2 available sizes of the Tiara mitral bioprosthesis.

Contrast-enhanced gated CT data acquisition of the entire cardiac cycle was used for the preprocedural analyses of the mitral annulus, subvalvular complex, LV, LVOT, and aortic prosthesis.[12,13] CT data including the entire rib cage were used to determine the optimal intercostal space for transapical access.

Anatomic eligibility criteria as determined by the CT included the following:

Mitral annulus area and perimeter to fit the available Tiara sizes; the degree of potential contact between the prosthetic valve tabs and the LV walls; and the potential risk for LVOT obstruction, which was virtually assessed by simulating the implanted device into the CT dataset with subsequent planimetry of the anticipated neo-LVOT cross-sectional area.

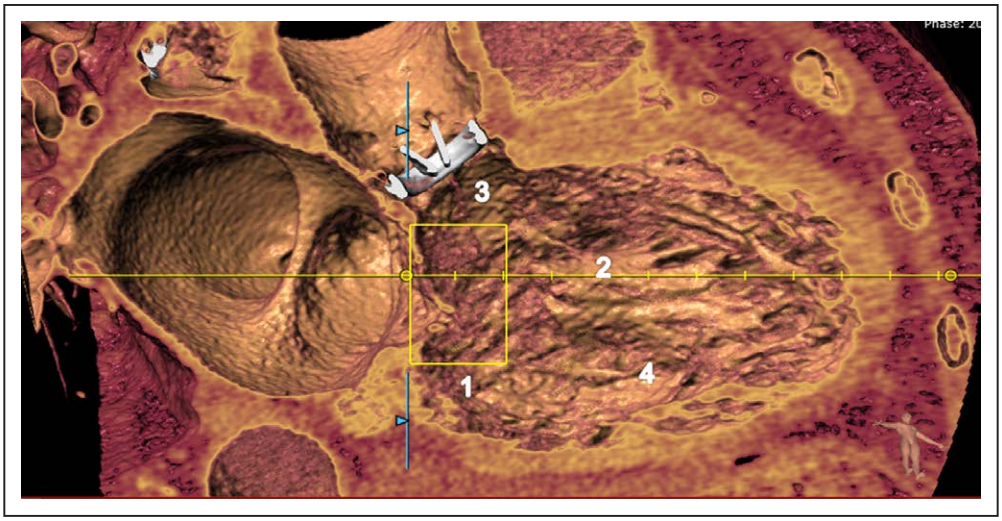

Figure 1. Virtual implant of a 35mm Tiara device into a patient with previous mechanical aortic valve replacement, showing non-obstructive left ventricular outflow tract.
Top, The Tiara valve is anatomically shaped to fit the asymmetrical, D-shaped mitral annulus. Currently, there are 2 valve sizes available, 35 mm and 40 mm, and the delivery catheter is 32F and 36F accordingly. The atrial portion of the valve is designed to fit the atrial portion of the mitral annulus. Ventricular anchoring structures are designed to secure the valve onto the fibrous trigones and posterior shelf of the sub-annulus. The delivery device comprises a self-dilating tip with a single turn-knob mechanism to allow controlled deployment and is designed to directly enter the left ventricular apex without a delivery introducer sheath. **Bottom**, Atrial view of the D-shaped Tiara in its open and closed positions.

Only patients with predicted neo-LVOT area of ≥2.0 cm^2 at end systole were considered eligible for treatment[14] (Figure 2).

Procedure

Tiara implantations were performed under general anesthesia via a transapical approach under TEE and fluoroscopic guidance. Through a left mini-thoracotomy, a needle puncture was performed and a J-tip wire introduced across the MV and into the left atrium. The Tiara TMVR delivery system was introduced directly over the wire across the MV, and the atrial portion of the prosthesis was unsheathed, properly oriented, and aligned with the native D-shaped mitral annulus. The delivery system and the valve were then pulled back to seat the atrial part of the valve onto the atrial aspect of the mitral annulus, and the ventricular anchors were then released to secure the valve before it was completely released on a beating heart. Echocardiographic evaluation of the anatomy of the heart, the performance of the prosthetic mitral and aortic valves, and the presence of LVOT gradient, were performed at the completion of the implantation procedure, before hospital discharge, and at 30 days.

End Points

The end points of our study were the occurrence of ≥1 of the following adverse events post-Tiara implantation: periprocedural and ≤30-day death, MI, stroke, and major bleeding; the need to convert to an open chest surgery; the need for a cardiopulmonary support system; the occurrence of a device migration; postimplantation (>trivial) MR or paravalvular leak; and the presence of hemodynamically significant LVOT gradient.

Statistical Analysis

Continuous variables are expressed as mean±SD, and categorical variables are expressed as n (%). Data analyses were performed using the Statistical Package for Social Sciences (SPSS), version 24 (IBM, Inc, Chicago, IL).

RESULTS

From 2015 to 2017, 12 consecutive patients with severe symptomatic MR, as determined by the Echo Core Laboratory and the Central Screening Committee, and

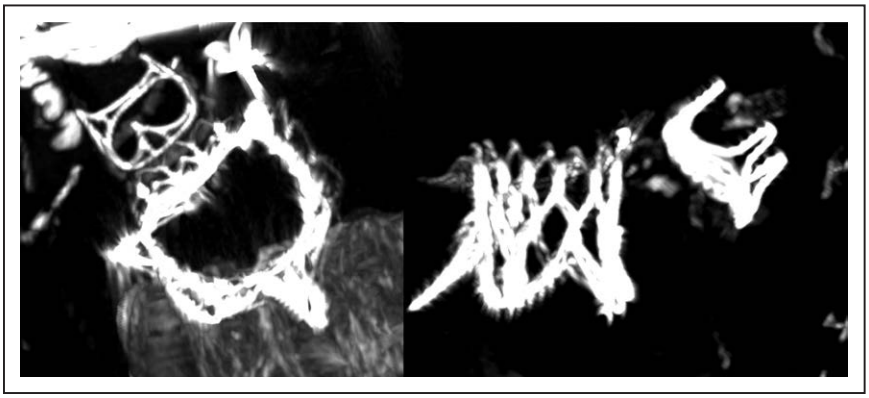

Figure 2. Preoperative computed tomography (CT) with cloning a simulated device-specific contour into the CT image, demonstrating virtual Tiara implantation. Demonstrated proper anatomic fit, unobstructed left ventricular outflow tract (LVOT) and lack of interaction with a mechanical aortic valve (**left**), and measurement of the predicted neo-LVOT area in the short-axis view (**right**).

previous AVR were treated with transapical implantation of the Tiara bioprosthetic valve. All were considered high surgical and prohibitive risk and unsuitable for alternative approved mitral repair or replacement procedures by the local heart team. TMVRs were performed either under compassionate use programs or as part of the TIARA-I early feasibility clinical trial. Two additional Tiara candidates with previous AVR were excluded. One because of likelihood of interference with the prosthetic aortic valve and a high degree of potential septal contact and a small neo-LVOT, and the second candidate was excluded because of potential for long-term interaction with a low-placed aortic bioprosthesis. Among all the other patients who were considered as screen failure for Tiara, previous AVR and potential LVOT obstruction was not the reason of exclusion.

All 12 patients had at least 1 previous surgical AVR. Among this group, 5 had mechanical aortic prosthesis, 7 had aortic bioprosthesis, and 1 had transcatheter aortic valve in valve implantation. Six of the patients had a history of at least 2 previous AVR surgeries, 1 patient had aortic root replacement, 2 patients had MV repair, and 5 had prior coronary bypass grafting surgery. A summary of the patients' clinical characteristics and their estimated surgical risk is presented in Table 1.

In all patients, the predicted post-TMVR LVOT area as determined by CTA at 70% systole was >2.0 cm^2.

Table 1. Patient Demographics

		Range
Male sex	11 (92%)	
Mean age, y	75±6	68–82
Aortic surgical valve replacement	12	
Mechanical prosthesis	5 (42%)	
Bioprosthesis	7 (58%)	
Aortic valve in valve	1 (8%)	
Prior MV repair (ring)	2 (17%)	
Prior CABG surgery	5 (42%)	
Chronic atrial fibrillation	7 (58%)	
Pacemaker/ICD/CRTD	9 (75%)	
Chronic kidney disease (eGFR<45)	9 (75%)	
Mean STS risk score, %	10.5±4.4	4.3–18.5
Mean EuroSCORE II, %	12.4±3.7	7.8–18.0
Mean baseline LVEF, %	35.5±5%	30%–45%
Mean systolic pulmonary artery pressure, mm Hg	58±22	27–107
NYHA class II	1	
NYHA class III	10	
NYHA class IV	1	

CABG indicates coronary bypass grafting; CRTD, cardiac resynchronization device; eGFR, glomerular filtration rate; ICD, internal cardiac defibrillator; LVEF, left ventricular ejection fraction; MV, mitral valve; NYHA, New York Heart Association; and STS, Society of Thoracic Surgery.

Table 2. Procedural and Periprocedural Outcomes

Procedural success	12 (100%)
Periprocedural and 30-d death/stroke/MI/bleeding	0
Conversion to open chest surgery	0
Cardiopulmonary support	0
Device migration	0
LVOT obstruction	0
Interference with aortic prosthesis	0
Postprocedural MR >trivial	0
Postprocedural paravalvular leak	0
Access site complication	0
Postprocedural pacemaker implantation	0

LVOT indicates left ventricular outflow tract; MI, myocardial infarction; and MR, mitral regurgitation.

The MR pathogenesis was functional (secondary) in 6, primary/degenerative in 2, including 1 patient with rheumatic MV disease, and mixed pathogenesis in 4 patients.

Baseline mitral annulus area and circumference were in the range of 6.6 to 12.5 cm^2 and 9 to 13 cm, respectively, as measured by CTA. All 12 transapical Tiara implantations were completed successfully and uneventfully, with optimal alignment and anchoring of the D-shaped prosthetic Tiara valves. There was no conversion to open heart surgery or need for mechanical hemodynamic support. MR was eliminated immediately post-implantation, and the degree of MR at predischarge and at 30-day follow-up echo was none or trace. Procedural success and device success rates were 100%. There were no cases of periprocedural and 30-day mortality, MI, stroke, bleeding, or need for pacemaker implantation.

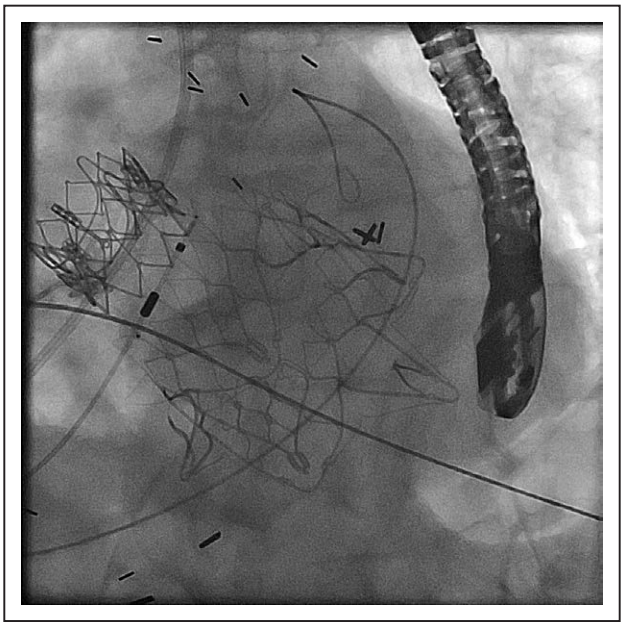

Figure 3. Profile and enface views of postimplant computed tomography of a Tiara valve in a patient with preexisting Carpentier-Edwards Perimount bioprosthesis.

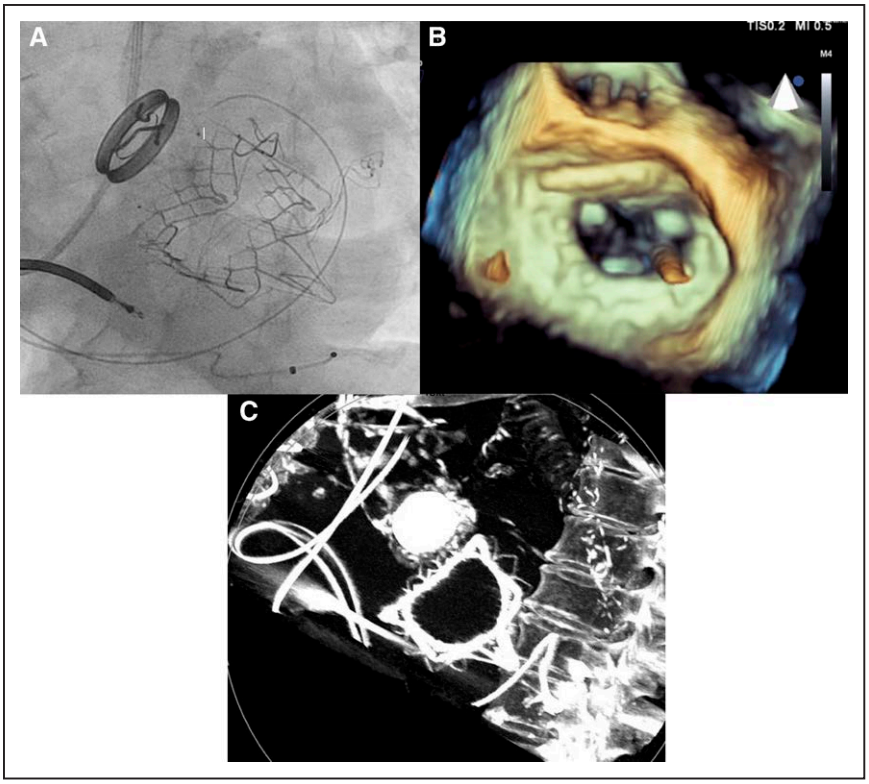

Figure 4. Images of Tiara implant in a patient with a Medtronic Hall mechanical aortic valve.
A, Postprocedural cineangiography. **B**, 3-dimensional postprocedural echo of the Tiara and the bileaflet mechanical aortic valve. **C**, 30-d postprocedure computed tomography.

Baseline LVOT pressure gradient was measured at the beginning of each procedure. No pressure gradient was measured in any of the 12 patients. There was no LVOT gradient measured by echo and by direct catheter measurement in any of the patients. There was no valve malposition or valve migration detected by postprocedural or predischarge and 30-day echo (Table 2).

Preprocedural factors, such as MR pathogenesis (primary, secondary, or mixed), type of aortic prosthesis (mechanical or biological), number of previous AVR surgeries or other heart surgeries, and previous MV repair surgery, did not influence procedural success, duration, or complexity of the procedure.

No interactions between the aortic prostheses and the Tiara valve during the implantation procedure or at follow-up were noted in any of the patients (Figures 2 through 4).

DISCUSSION

This is the first description of periprocedural and short-term outcomes of TMVR in patients with previous surgical AVR. In this retrospective analysis, we describe, for the first time, the periprocedural and short-term outcomes of patients with severe MR and previous AVR treated with the Tiara TMVR system. We show that with an effective patient screening, and a valve design that fits into the native mitral apparatus, LVOT obstruction is avoided and that preexisting aortic prosthesis does not add any complexity to the TMVR procedure or to its results.

The development of TMVR therapy for MR has been slow and challenging because of the complex anatomy and the great heterogenic pathogenesis of the MR.

The field of TMVR is only in its first steps of development, and the rate of its evolution into a practical and established interventional procedure, mature enough to treat patients, will be much slower than that of TAVR. Data published and presented by the different groups of researchers on various aspects of their TMVR experience can facilitate the fruition of the TMVR field.

The unique features and complex anatomy of the native mitral apparatus require a complex device design.[1,15] TMVR device must fit into the multiplanar and asymmetrical native mitral apparatus, achieve good apposition and anchoring to the dynamic movement of the mitral annulus, bear the high LV systolic closing gradient, and effectively seal and prevent paravalvular leak. Unlike transcatheter aortic valves, most MV implantations are performed in the absence of significant annular calcification. This limits the amount of radial force the mitral prosthesis can apply to achieve adequate fixation without altering the shape of the native mitral annulus and the anatomy of the base of the heart. Furthermore, protrusion of the bulky frame of the valve into the LV may cause LVOT obstruction, interfere with the function of a native or prosthetic aortic valve, interact with the anterior MV leaflet, and potentially cause systolic anterior motion. The anatomy of the LVOT exhibits significant interindividual variability and is influenced mainly by the configuration of the intraventricular septum, LV size, and aortomitral angulation.[14,16]

The coexistence of aortic valve disease, and especially the presence of a prosthetic aortic valve, might add an additional component of complexity to the challenging TMVR procedure with possible increased risk. At present, some evolving TMVR technologies are excluding patients with preexisting aortic prosthesis from their studies.

The Tiara valve assembly is asymmetrical and shaped to match the natural geometry of the native mitral apparatus and to prevent impingement of the aorta or LVOT. The anchoring and fixation of the device does not rely solely on radial force, and by design, the D-shaped valve is sparing the LVOT. The ventricular portion of the device expands within the subannular space of the LV to draw the native anatomy, as well as the anterior mitral leaflet against the body of the valve to prevent paravalvular leak and LVOT obstruction by systolic anterior motion.

Here, we demonstrate that the presence of a prosthetic aortic valve, either mechanical or biological, did not add any extra complexity to the procedure. On the contrary, the presence of the prosthetic valve added a helpful fluoroscopic marker, which further assists with the process of device alignment.

In conclusion, TMVR with the Tiara valve in patients with preexisting aortic valve prosthesis was safely and successfully implanted and was not associated with LVOT obstruction or with any other mechanical or hemodynamic interference. The design of this device affords a stable and predictable implantation, representing a reasonable alternative to treat this particular subset of patients.

ARTICLE INFORMATION

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Disclosures

Dr Cheung serves as a consultant at Neovasc, Inc, and as a principal investigator for TIARA-I Early Feasibility Trial. Dr Banai serves as a medical director at Neovasc, Inc. Dr Blanke provides core lab services for Neovasc for which he receives no direct compensation and is a consultant to Neovasc. Drs Denti and Deuschl are a consultant to Neovasc, Inc. The other authors report no conflicts.

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